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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,571	07/13/2000	Paul Harris	5951.010-US	4949
25907	7590	07/21/2005		
NOVOZYMES BIOTECH, INC. 1445 DREW AVE DAVIS, CA 95616			EXAMINER PRIEBE, SCOTT DAVID	
			ART UNIT 1633	PAPER NUMBER

DATE MAILED: 07/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 09/615,571	<b>Applicant(s)</b> HARRIS ET AL.	
	<b>Examiner</b> Scott D. Priebe, Ph.D.	<b>Art Unit</b> 1633	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 13 July 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in the above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 13 July 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.

6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 125-128.

Claim(s) objected to: 105-107, 112 and 116.

Claim(s) rejected: 100, 102-104, 109-111, 114, 115, 117 and 119-124.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_

13. ☐ Other: \_\_\_\_\_.

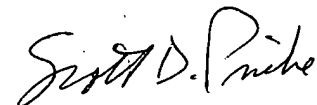
Scott D. Priebe, Ph.D.  
 Primary Examiner  
 Art Unit: 1633

Continuation of 11. does NOT place the application in condition for allowance because:

Independent claims 100 and 117 have been amended to limit the claimed nucleic acid sequence to those that encode a naturally occurring polypeptide having phospholipase B activity. The claims do not require that the nucleic acid sequence be naturally-occurring, i.e. isolated from nature. Part (a) of claim 100 has the effect of limiting the naturally-occurring polypeptide to those that are at least 90% identical to SEQ ID NO: 2. Parts (b) and (c) of claim 100 and claim 117 place no constraints on the degree of sequence similarity between the naturally-occurring phospholipase B encoded by the claimed nucleic acid sequence and SEQ ID NO: 2. They place constraint only on the degree of sequence similarity between the claimed nucleic acid sequence and SEQ ID NO: 1. The nucleic acid sequence may be man-made and differ from that of the naturally-occurring nucleic acid sequence by replacing nucleotides that would not affect the amino acids encoded, i.e. wobble-bases. In the case of claim 117, the clone is not required to contain nucleic acid cloned from a naturally-occurring source. For example, it also reads on clones produced by targeted mutagenesis of SEQ ID NO: 1 or targeted mutagenesis of a naturally occurring nucleic acid sequence encoding SEQ ID NO: 1. Consequently, parts (b) and (c) of claim 100 and claim 117 embrace embodiments wherein the naturally-occurring polypeptide has substantially less sequence similarity than 90% identity with SEQ ID NO: 2, but wherein wobble-bases of the naturally-occurring nucleic acid have been altered to increase their sequence similarity with SEQ ID NO: 1.

With respect to the rejection for lack of an adequate written description, Appellant reiterates the claim limitations and then merely asserts (reply, page 7) that one of skill in the art would not expect substantial variation among species embraced by the claims sharing the hybridization requirements, and that in combination with the coding function of DNA and level of skill in the art a representative number of species, i.e. 1 species, has been disclosed in order to demonstrate possession of the claimed invention. Similar assertions are made with respect to the limitations requiring at least 90% sequence identity between the encoded protein and SEQ ID NO: 2 or between the nucleic acid sequence and SEQ ID NO: 1. These assertions merely reiterate assertions made in the reply of 11/26/04, and have been fully addressed in the Office action of 1/11/05; page 7 of this Office action is particularly pertinent to the amended claims. As explained above, the claims do not require that the nucleic acid sequences be naturally-occurring, they may be man-made, so long as they encode a naturally-occurring phospholipase B. To envision the nucleic acid sequences of the invention, one requires knowledge of the amino acid sequence of a naturally-occurring phospholipase B, regardless of how one goes about determining such an amino acid sequence. Once the amino acid sequence is known, then one of skill in the art could readily envision various nucleotide sequences that would encode it and satisfy the limitations on structural similarity between the claimed nucleic acid and SEQ ID NO: 1. It remains that the specification describes a single species of naturally-occurring phospholipase B whose encoding nucleic acid is within the bounds of the claims, and if one of skill in the art were informed of an amino acid sequence that encoded a phospholipase B, one could readily determine whether a nucleic acid sequence could be made that met the limitations of the claims, BUT one could not determine from this information whether the phospholipase B were naturally-occurring. Hence, there is no predictive value in SEQ ID NO: 1 or 2 with respect to the amino acid sequence of a different naturally-occurring phospholipase B, and hence its encoding nucleic acid sequence.

With respect to the rejection for lack of enablement, Appellant points out that the specification teaches how to screen libraries of nucleic acids isolated from natural sources and compare nucleotide and amino acid sequences, and then asserts that one would know how to make the claimed nucleic acids commensurate in scope with the claims. However, Appellant has ignored two critical issues raised in the rejection and discussed in the Office action of 1/11/05. First, the phospholipase B of SEQ ID NO: 2 has very little sequence similarity with any previously known phospholipase B, and in fact has more sequence similarity with previously known phospholipase C polypeptides. Second, and more important, the specification fails to identify any natural source for the claimed nucleic acid sequence than *Aspergillus oryzae*, and discloses a process known to be operable for obtaining the claimed nucleic acid sequences only using *A. oryzae* nucleic acid. The claims are not limited to nucleic acids isolated from *A. oryzae*. Thus, the guidance in the specification is not commensurate in scope with that of the enabling disclosure.



SCOTT D. PRIEBE, PH.D.  
PRIMARY EXAMINER